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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 3 1 2015

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Lamar Smith
Chairman
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your July 27, 2015, letter to the Environmental Protection Agency in which you requested responses to Questions for the Record following the July 9, 2015, hearing before the Committee on Science, Space, and Technology entitled, "Examining EPA's Regulatory Overreach."

The responses to the questions are provided as an enclosure to this letter. If you have any further questions, please contact me, or your staff may contact Josh Lewis at lewis.josh@epa.gov or (202) 564-2095.

Sincerely,

Laura Vaught

Laura Vaught
Associate Administrator

Enclosure

QUESTIONS FOR THE RECORD
The Honorable Jim Bridenstine (R-OK)
U.S. House Committee on Science, Space, and Technology

Examining EPA's Regulatory Overreach

Question 1

It is my understanding that the EPA conducts benefit analyses towards the end of a pesticide approval process, or renewal. I also understand that only after a risk has been identified will EPA examine the balance between risks and benefits.

However, regarding the EPA-issued memo on "Benefits of Neonicotinoid Seed Treatments to Soybean Production," the EPA undertook this study prior to completing a preliminary risk assessment for neonics. USDA reacted very negatively to the EPA study stating in a letter that that "as a whole, USDA disagrees with that [EPA] assessment" and cautioned EPA about "releasing a premature assessment" that would be "an additional and unnecessary burden" on farmers.

I do not understand why you did not work with USDA on this agriculture-related assessment done as part of the more complete analysis which presumably is underway. This appears to me to me as an effort to influence the market; rather than follow the science. Are you employing a precautionary approach rather than a clear science-based approach?

Response to Question 1

The EPA conducted its assessment of the benefits on neonicotinoid treatments to soybean seed as part of the ongoing registration review for this class of compounds that began in 2008. As part of that re-evaluation process, the agency is assessing the potential risks posed by these treatments and the benefits that these uses provide to agriculture. In the process of assessing the risks posed by the neonicotinoids, the EPA became aware of several studies, including one that had been co-authored by a USDA scientist, studying whether neonicotinoids provided benefits when used as treatments to soybean seed in South Dakota in 2009 and 2010. Those studies did not evaluate the benefits of those seed treatments to soybean producers across the range of regions, under different soybean prices, or under different growing conditions that are typical of U.S. soybean production. Nor did those studies evaluate the impact of neonicotinoid seed treatment on pollinators or the impact of alternative pesticide treatments such as foliar sprays on pollinators.

Based in part on those studies, the EPA decided to evaluate the benefits of the soybean seed treatment use. The EPA document analyzes how neonicotinoid seed treatments are currently used in soybeans (e.g., target pests), the alternatives to seed treatments, and the biological and economic benefits of seed treatments compared to other pest control options.

As part of that analysis, the EPA asked USDA to provide data from USDA's regional Integrated Pest Management (IPM) centers, funded through grants from the National Institute of Food and Agriculture (NIFA), on the use and importance of neonicotinoid seed treatments in the production of 17 crops, including soybeans. Those data are not publicly available and are still preliminary.

Additionally, the EPA met and shared the preliminary benefits analysis document with USDA's Office of Pest Management Policy (OPMP) on three occasions for their review. Prior to publication, the EPA corrected one reference in response to the preliminary comments provided by OPMP's review, pointed OPMP to areas of the document that address uncertainties that OPMP raised regarding the regional/conditional need for seed treatment, worked with USDA on obtaining additional information and input from IPM Centers, and explained why the EPA did not consider other USDA/OPMP comments. (See Response to Question 4 for more information as well the attached email communication dated October 15, 2014).

Consistent with our transparency principles, the EPA sought public input on its draft assessment. The agency expects to finalize this analysis later this year and will consider the results in determining whether risk mitigation is necessary for the neonicotinoids. As part of this ongoing re-evaluation process, the EPA will again seek comment from USDA and the public on the analysis and any identified risk mitigation before finalizing the agency's risk management decision.

Question 2

Your recent actions - a moratorium on new registrations, your study on soybean seed treatments which USDA severely criticized, and the new label restrictions) are premised on the belief that honey bees are disappearing; but USDA data doesn't support that position.

I am informed that honey bee populations have had their ups and downs but have steadily risen in the United States over the past 10 years. USDA reported that the number of honey bee colonies grew to 2.74 million, the highest level in many years. A University of Maryland study, conducted with EPA and USDA, found that "honey bees are not harmed by realistic exposures" to neonic pesticides. The lead author of the study, Dr. Galen Dively, noted that neonic pesticides are "very safe, an order of magnitude safer than organophosphates."

Further, a USDA press release of May 15 last year said that fewer colony losses occurred in the U.S. over the winter of 2013-2014 than in recent years. A recent University of Maryland three-year field study, in which USDA and EPA participated, showed no material impact on hive health from neonics, even at doses well above those bees would encounter in the field. Does EPA now disagree with that University of Maryland study which EPA helped write?

Response to Question 2

The recently released *National Strategy to Promote the Health of Honey Bees and other Pollinators*[1] discusses the losses of managed honey bee colonies used to produce honey in the U.S. based on data collected by the USDA National Agricultural Statistics Service (NASS). Managed colony numbers from 1945 to 2006 (depicted in **Figure 1**) illustrate a relatively steady decline in managed honey bee colonies from 1947 to roughly 1995. A second graph (**Figure 2**; reproduced from the National Strategy) depicting NASS data from 1965 to 2014 illustrates that the number of honey bee colonies used for honey production from 1995 to 2009 was relatively

[1] White House 2015. National Strategy to Promote the Health of Honey Bees and other Pollinators. Pollinator Health Task Force. May 19, 2015. Can be found at the following website: https://www.whitehouse.gov/blog/2015/05/19/announcing-new-steps-promote-pollinator-health.

constant around 2.5 million and from 2010 to present the numbers have been around 2.7 million. It is uncertain whether these data could be construed to depict a "steady increase." However, what the graph does not depict is the level of effort and expense that beekeepers are having to exert to maintain colony numbers.

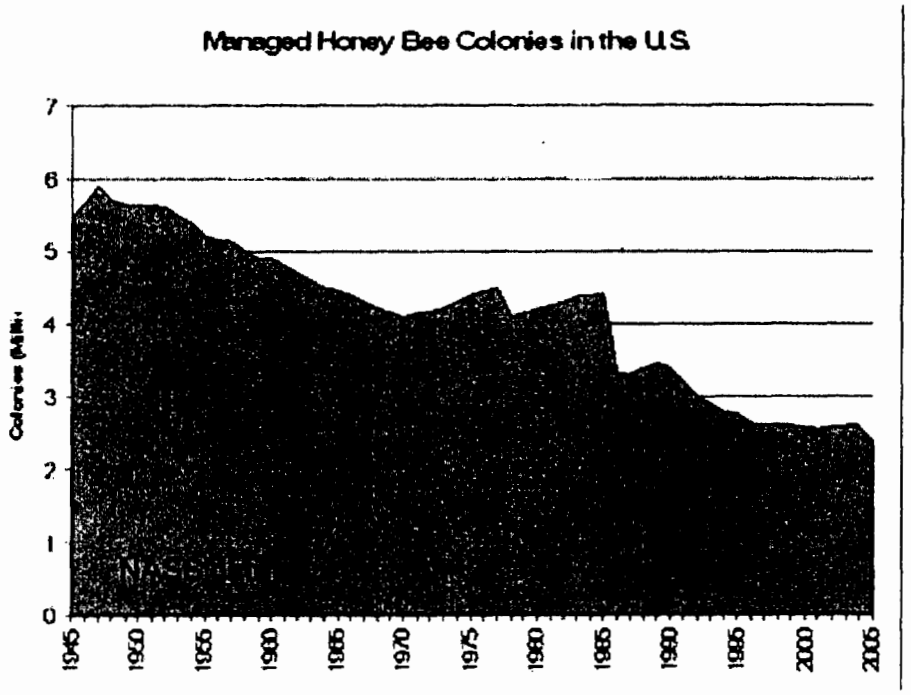

Figure 1. Number of managed honey bee colonies in the U.S from 1945 - 2006 based on National Agricultural Statistics Service (NASS) data.

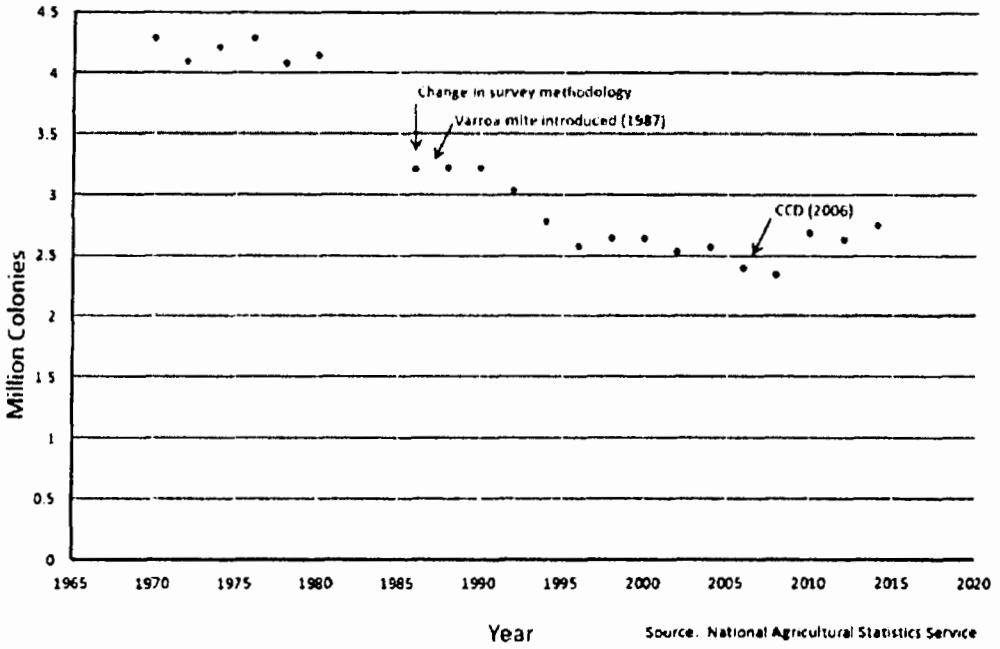

Figure 2. Numbers (in millions) of managed honey bee colonies in the United States used for honey production by year based on USDA National Agricultural Statistics Service (NASS) survey data. The gap between 1982 – 1986 reflects the period when the survey was not conducted. The figure illustrates when the Varroa mite was introduced into the United States in 1987, and when Colony Collapse Disorder was first documented in 2006 (reproduced from White House 2015).

The USDA press release of May 15, 2014, as well as more recent data on overwinter losses from 2014 – 2015, indicate losses less than the national average of 31%, based on data collected (beginning in 2006) through a winter loss survey of beekeepers[2]. However, as noted in the President's National Strategy on Pollinator Health[3], these losses reported by researchers at the University of Maryland "*far exceed the 15-17% overwintering loss rate that commercial beekeepers have indicated is an economically sustainable average*[4]. *When overwintering losses are coupled with colony losses occurring during other times of the year, annual losses can be considerably higher*[5]. *This is particularly notable in the 2014-15 preliminary report of 27.4% summer colony loss in the Bee Informed survey of a subset of national beekeepers, for total annual losses of 42.1% of colonies*[6]."

[2] Steinhauer, N.A., *et al.* 2015. Colony Loss 2014 – 2015: Preliminary Results. http://beeinformed.org/2015/05/colony-loss-2014-2015-preliminary-results

[3] *Ibid* White House 2015.

[4] Steinhauer, N.A., *et al.* 2013. A National Survey of Managed Honey Bee 2012–2013 Annual Colony Losses in the USA: Results from The Bee Informed Partnership. *Journal of Apicultural Research* 53.1 (2013): 1-18.

[5] *Ibid* Steinhauer *et al.* 2013.

[6] *Ibid* Steinhauer *et al.* 2015

In the article by Dively *et al.* 2015[7], the authors noted that *"[G]iven the weight of evidence, chronic exposure to imidacloprid at the higher range of field doses (20 to 100 µg/kg) in pollen of certain treated crops could cause negative impacts on honey bee colony health and reduced overwintering success, but the most likely encountered high range of field doses relevant for seed-treated crops (5 µg/kg) had negligible effects on colony health and are unlikely a sole cause of colony declines."* While an EPA staff member (Dr. Alaa Kamel) is listed as a co-author on the study and the EPA assisted in the residue analyses, the overall study conclusions should not be construed as representing the position of the EPA. The agency is considering the Dively *et al.* study of imidacloprid just as it would any study published in the open literature, *i.e.*, in terms of whether it meets the EPA evaluation guidelines for ecological toxicity data in the open literature[8]. That study, along with other lines of evidence deemed to be scientifically sound, will be considered in the initial risk assessment for imidacloprid, which is scheduled for release in December 2015.

Imidacloprid and other chemicals belonging to the nitroguanidine-substituted neonicotinoids are currently undergoing evaluation as part of the EPA Registration Review program, and the decisions for these compounds are scheduled for the 2016 – 2017 timeframe. The EPA is considering multiple lines of evidence regarding potential exposure to and effects from these compounds, and the EPA has required that the registrants also conduct studies in support of registration review. At this time, the EPA has not reached a final decision in the registration review process regarding imidacloprid or any other nitroguanidine neonicotinoid to determine whether these pesticides meet the Federal Insecticide, Fungicide and Rodenticide Act standard of no unreasonable adverse effects to human health or the environment. The data and conclusions reached in a single paper are typically considered in combination with all available data in a weight-of-evidence approach.

Question 3

EPA, USDA, and the White House have stated that diseases, loss of habitat, parasites, pests, bacteria, and bee malnutrition are some of the major culprits regarding stresses on bee health. Key scientists working with USDA determined that the deadly Varroa Destructor mites could be responsible for over 75 percent of the loss of bee hives in the United States. The leading scientist was Dr. Pettis with USDA's Agricultural Research Service. As EPA focuses on bee-health issues are you coordinating with USDA on this Varroa-mite problem?

Response to Question 3

The EPA has been working closely with the U.S. Department of Agriculture Research Service Beltsville Bee Research Laboratory on the Varroa mite issue and on efforts to understand the potential role of pesticides in pollinator health. The EPA has also worked collaboratively with other federal agencies and with our international regulatory counterparts to understand the

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[7] Dively, G. P., M. S. Embrey, A. Kamel, D. J. Hawthorne and J. S. Pettis. 2015. Assessment of Chronic Sublethal Effects of Imidacloprid on Honey Been Colony Health. PLoS ONE 10(3): e0118748.doi:10.1371/journal.pone.0118748

[8] USEPA. 2011. Evaluation Guidelines for Ecological Toxicity Data in the Open Literature. http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_evaluation_open_literature.htm

factors associated with regional declines in honey bee populations. In addition, the EPA is a member of the USDA Colony Collapse Disorder (CCD) and Honey Bee Health Steering Committee.

Question 4

On April 6 of this year, EPA received comments from the USDA Chief Economist which stated that "as a whole, USDA disagrees with an [EPA] assessment" that there are no clear economic benefits to neonic seed treatments in soybeans. Further, those USDA comments note that USDA cautioned EPA about "releasing a premature assessment" on seed treatment benefits. USDA also pointed out that there would be "an additional and unnecessary burden" on farmers by publishing that report, and that USDA requests for more data were ignored by EPA before releasing the report. I am very concerned that it appears that EPA, in issuing that assessment, was more interested in politics than sound scientific facts. Did EPA allow USDA to review the October, 2014, seed treatment memo before it was released to the public?

If USDA reviewed the EPA memo ahead of time, please name those USDA officials who did the review and whether they provided any input to EPA?

If advance written comments were provided by USDA to EPA, please provide those comments to my office?

Response to Question 4

The EPA discussed its benefit analysis for soybeans with USDA on several occasions in 2014. USDA's Office of Pest Management Policy (OPMP) reviewed the preliminary benefits analysis document, and provided oral and written comments prior to publication. USDA's final written comments prior to publication of the analysis reflect the comments that USDA raised throughout the process and are attached.

Based on USDA's comments, the EPA corrected one reference in the document, pointed USDA/OPMP to areas of the document that address uncertainties that USDA/OPMP raised regarding the regional/conditional need for seed treatment, incorporated additional information and input from IPM Centers, and explained why the EPA did not consider other USDA/OPMP comments. (See attached email dated October 15, 2014).

After the preliminary review and discussion in the summer of 2014, USDA helped facilitate the collection of additional information via USDA's Integrated Pest Management Centers. Twenty-one entomologists from 17 states responded to the IPMC questionnaire with preliminary and non-public data for 17 crops. Their responses included information on the most regionally important pests, the effectiveness of neonicotinoid seed treatments in comparison to alternatives, the value of preventative pest control in their regions, and their general thoughts on seed treatment benefits for 17 different crops. The EPA incorporated information on soybean treatment only into the October 2014 document.

On pesticide matters, the EPA primarily coordinates with USDA/OPMP and relies on OPMP to coordinate with other parts of USDA. OPMP was established under the Farm Bill and works

under the direction of the Deputy Secretary. While OPMP is administratively under the Agricultural Research Service (ARS), OPMP is a policy office and does not do research. ARS and OPMP roles are very clearly different and separate. USDA's Office of the Chief Economist (OCE) submitted their comments after publication of the soybean benefits document and as part of the public comments. EPA also received official comments from ARS on April 6, 2014. Both sets of submitted comments from USDA (one from USDA/ARS and one from USDA/OCE) are attached for reference.

Question 5

I am told that EPA and USDA coordinated with the University of Maryland on a 3-year, comprehensive, "field-based" study and determined that "honey bees are not harmed by realistic exposure" to a neonic pesticide. That university study and the USDA research -- coupled with confirming data from the continent of Australia which is not infested with Varroa destructor mites -- could indicate that properly-applied neonic pesticides are effective and safe since as use of neonic pesticides increased in Australia, the honey bee populations in Australia were "not in decline; instead there have been significant increases" according to reports from Australia.

Has EPA reviewed the Australian study which highlighted the lack of Varroa mites and pointed out significant bee-colony increases in Australia at the same time that neonic pesticides were used?

Response to Question 5

With respect to the University of Maryland research conducted by Dively *et al.* 2015[9], the authors noted that *"[G]iven the weight of evidence, chronic exposure to imidacloprid at the higher range of field doses (20 to 100 µg/kg) in pollen of certain treated crops could cause negative impacts on honey bee colony health and reduced overwintering success, but the most likely encountered high range of field doses relevant for seed-treated crops (5 µg/kg) had negligible effects on colony health and are unlikely a sole cause of colony declines."* While an EPA staff member (Dr. Alaa Kamel) is listed as a co-author on the study and the EPA assisted in the residue analyses, the overall study conclusions should not be construed as representing the position of the EPA. The agency is considering the Dively *et al.* study of imidacloprid just as it would any study published in the open literature, *i.e.*, in terms of whether it meets the EPA evaluation guidelines for ecological toxicity data in the open literature[10].

The Agency is also aware of other studies by Dr. Dively[11] [12] as well as other researchers at the University of Maryland who are examining factors associated with honey bee declines. As noted

[9] Dively, G. P., M. S. Embrey, A. Kamel, D. J. Hawthorne and J. S. Pettis. 2015. Assessment of Chronic Sublethal Effects of Imidacloprid on Honey Been Colony Health. PLoS ONE 10(3): e0118748.doi:10.1371/journal.pone.0118748

[10] USEPA. 2011. Evaluation Guidelines for Ecological Toxicity Data in the Open Literature. http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_evaluation_open_literature.htm

[11] Dively G. P. and A. Kamel. 2012. Insecticide residues in pollen and nectar of a cucurbit crop and their potential exposure to pollinators. J Agric Food Chem 60: 4449–4456. doi: 10.1021/jf205393x PMID: 22452667

[12] Pettis JS, D. vanEngelsdorp, J. Johnson, and G. Dively. 2012. Pesticide exposure in honey bees results in increased levels of the gut pathogen Nosema. Naturwissenschaften. 2012; 99: 153–158. doi: 10.1007/s00114-011-0881-1 PMID: 22246149

in the response to Question 2, the EPA considers multiple lines of evidence in assessing risks of pesticides. Open literature studies meeting the EPA evaluation standards will be considered in the risk assessment process.

The EPA is also aware of the 2014 publication by the Australian Pesticides and Veterinary Medicines Authority (APVMA) "*Neonicotinoids and the Health of Honey Bees in Australia*"[13]. This report was compiled by APVMA to establish whether:

a) the use of neonicotinoid insecticides in Australia is presenting any increased risk to the health of honeybees than other pesticides that have been in use for many years; and,

b) the current APVMA data requirements for testing of insecticides are adequate to address scientific concerns about subtle effects of neonicotinoids (and other pesticides) in honey bees, which have been suggested as impacting their ability to pollinate plants and collect honey.

The report noted the lack of consensus on the multiple factors (*i.e.*, pesticides, parasites, viruses [diseases], climate change, bee nutrition, lack of honey bee genetic diversity, and beekeeping practices) associated with regional declines in honey bee colony numbers in other areas of the world. At that time, honey bee populations in Australia were not in decline and insecticides were not considered a "highly significant issue" when used according to label instructions and/or when beekeepers and growers communicate effectively. Also, neonicotinoids were not considered uniquely toxic to bees since other insecticides can be also be highly toxic to bees. The report noted that in general, few adverse impacts have been observed at doses to which pollinators might be exposed in the field with the "*exception of those well-documented cases in several European countries and in Canada of bee mortality caused by acute exposure of bees to neonicotinoid dusts generated during the planting of insecticide-coated maize seed and that there has been only a limited number of cases of poisoning of bees with neonicotinoids in countries where monitoring (either passive or active) has been carried out.*" The publication also noted that the persistence of certain neonicotinoids and their ability to translocate within plants "*presents a greater environmental hazard than other less persistent and/or less mobile insecticides even though Australian honeybee populations are not in decline, despite the increased use of this group of insecticides in agriculture and horticulture since the mid-1990s.*"

As noted in response to Question 3 and consistent with the *National Strategy to Promote the Health of Honey Bees and other Pollinators*, the EPA is engaged on a number of domestic and international fronts to understand the factors associated with regional declines in honey bee populations, to advance the science for examining the role that pesticides may play in these declines, and to implement appropriate mitigation where needed.

It is correct that Australia does not currently have Varroa mites and that the country has not experienced the regional losses in honey bee colonies similar to those in the U.S. and other parts of the world. However, Australian beekeepers have not been as heavily involved with pollination

[13] http://archive.apvma.gov.au/news_media/docs/neonicotinoids_overview_report_february_2014.pdf

services as commercial beekeepers in the U.S., where bees may be brought into closer proximity with agricultural areas where a range of chemicals (including neonicotinoids) may be in use.

Question 6

In any decision-making process regarding the use of neonics in the U.S. will the EPA take into account the reports from some European nations where neonics were banned -- which resulted in major harm to crop production, farmers, and farm communities without compensating benefits to bees?

Response to Question 6

Neonicotinoids were not banned per se. The European Commission adopted a proposal to restrict the use of three pesticides belonging to the neonicotinoids family (clothianidin, imidacloprid and thiamethoxam) for seed treatment, soil application (granules) and foliar treatment on bee attractive plants and cereals for a period of two years. Specifically, the restrictions are enforced across all EU Commission countries. The restrictions began December 2013, so should be ending December 2015.

The EPA has been monitoring the actions and impacts of the regulatory actions taken by regulatory officials in Europe. As appropriate, during the registration review for the neonicotinoids, the EPA will consider any reliable data that are submitted to the agency documenting the impacts on pest control and crop yields resulting from these regulatory actions.

Question 7

In the mid-South neonics protect cotton, rice, and soybean production which are very important to our economy, farmers, and to consumers. Many farm operators today are very precise in how they run their businesses and I am certain they have a very good understanding of the value of seed treatments. I understand that EPA issued a report on the economic benefits to farmers of using seed treatments on soybeans. In conducting the EPA soybean assessment, did EPA talk to any farmer in my state or my state department of agriculture to get relevant data?

If so, please provide more details about those discussions and summaries of that farm-related input, if any, to my office.

Response to Question 7

On pesticide matters, the EPA works closely with USDA to obtain input from leading researchers, extension experts, producers, growers, and other industry representatives with a broad range of perspectives. For this particular assessment, USDA, through the North Central IPM Center (NC IPMC) helped to coordinate a questionnaire of the leading soybean research and extension experts in the United States. There were no respondents from Oklahoma to the NC IPMC questionnaire. However, experts from Mississippi, Louisiana, Arkansas, Missouri and Texas submitted comments and responses that were germane to soybeans and EPA included this information in the October 2014 assessment.

If farmers from Oklahoma or experts from the Oklahoma Department of Agriculture have any information that will help improve the EPA's assessment, the agency would be happy to receive

and evaluate this information along with the other comments we received. The EPA plans to respond to all substantive comments received via the public comment period and will consider possible revisions or an addendum to the assessment. The EPA will consider all submitted information before proposing any risk management decisions if risk mitigation is warranted.

Question 8

I understand that in Australia there are no Varroa Destructor mites, and there are few concerns about "colony collapse," and yet they use neonics in Australia much the same as in the U.S. In fact, the Australian government issued a report on bee health and the use of neonics. It found that "Australian honey bee populations are not in decline, despite the increased use of [neonics] in agriculture and horticulture since the mid-1990s" in Australia. These reports certainly seem represent very large, real-world examples of the lack of correlation between neonics and impaired bee health.

Have you reviewed these Australian government reports and do you believe they are instructive and should be considered in any decisions to limit the use of neonics in the U.S.?

Response to Question 8

As noted in response to Question 5, the EPA is aware of the 2014 publication by the Australian Pesticides and Veterinary Medicines Authority (APVMA) "*Neonicotinoids and the Health of Honey Bees in Australia*"[14]. EPA has also updated APVMA and their stakeholders on EPA's understanding of the neonicotinoids and pollinator health. The extent to which the use of neonicotinoids represents a risk to bees and other insect pollinators is currently under evaluation by the EPA based on the *Guidance for Assessing Pesticide Risks to Bees*[15] released by EPA in 2014.

This guidance was developed in part based on a Society of Environmental Toxicology and Chemistry global workshop in 2011 on developing a risk assessment process for bees, the proceedings[16] of which were published in 2014. Representatives of the Australian government participated in the workshop and contributed to the tiered risk assessment process currently used by EPA for bees. Similar to the EPA's process for evaluating risk for other types of wildlife, the agency will consider all available data, including studies conducted in Australia in assessing the risk of neonicotinoids to bees and the full weight of evidence will be used to support EPA risk management decisions.

[14] http://archive.apvma.gov.au/news_media/docs/neonicotinoids_overview_report_february_2014.pdf

[15] USEPA, PMRA and CalDPR. 2014. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington DC, Health Canada Pest Management Regulatory Agency, Ottawa, ON, Canada, California Department of Pesticide Regulation, Sacramento, CA. http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

[16] Fischer, D., and T. Moriarty. 2014. Pesticide risk assessment for pollinators: summary of a SETAC Pellston Workshop. SETAC Press. http://www.setac.org/sites/default/files/executivesummarypollinators_20sep2011.pdf.

QUESTIONS FOR THE RECORD
The Honorable Bruce Westerman (R-AR)
U.S. House Committee on Science, Space, and Technology
Examining EPA's Regulatory Overreach
Monday, July 27, 2015

Questions for Administrator McCarthy
1. According to Cara Keslar's April 29th testimony in front of our Environment Subcommittee, Wyoming has submitted five demonstrations or petitions to EPA Region 8 for exceptional events decisions for stratospheric intrusions. According to Ms. Keslar, "Wyoming has only received one concurrence. The EPA has not acted on the other four demonstrations. The demonstrations were submitted between 2010 and 2013." Why is it taking EPA so long with these demonstrations and petitions? What kind of confidence does this track record give you with regard to future petitions under a lower standard?

Response to Question 1:

As mentioned in Ms. Keslar's testimony, EPA Region 8 has concurred on Wyoming's exceptional events demonstration for the June 14, 2012, stratospheric ozone intrusion event. The state's demonstration and EPA's subsequent concurrence were the result of a successful collaboration between technical and policy staff at both agencies. We look forward to building on this partnership as we work on future exceptional events demonstrations submitted by the state of Wyoming.

We acknowledge that there are a number of demonstrations that EPA has yet to take action on. In the case of exceptional events demonstrations related to stratospheric ozone intrusion, this delay is often due to the complexity of these unique atmospheric events and the need to meet the requirements of the 2007 Exceptional Events Rule. EPA is currently drafting revisions to the Exceptional Events Rule aimed at streamlining the overall exceptional events process. EPA anticipates proposing these revisions in fall 2015 through a public notice and comment rulemaking effort. EPA expects that these rule revisions along with a compilation of best practices for communication and collaboration between the EPA and air agencies will improve the efficiency of the process by which air agencies identify and develop demonstrations for relevant exceptional events and the EPA reviews these submissions.

In addition, EPA often prioritizes exceptional events demonstrations by their impact on a state's ability to meet a National Ambient Air Quality Standard (NAAQS). If the air quality data associated with an exceptional events demonstration do not affect a near-term regulatory decision associated with a relevant NAAQS or if there is no other compelling reason for excluding data, EPA may lower the priority of taking action on that demonstration. After discussing this process with Wyoming, EPA Region 8 applied this approach to the five stratospheric ozone intrusion demonstrations submitted by Wyoming, including the concurred upon June 14, 2012 demonstration. Region 8 acted on the June 14, 2012, demonstration because the exceedances are associated with the Upper Green River Basin area, a current nonattainment area for the 2008 ozone NAAQS. The air quality data associated with the other four

demonstrations are not likely to influence future regulatory decisions affecting Wyoming, and therefore, Region 8 assigned a lower priority. Region 8 would review these other demonstrations in the future if they became significant – i.e., the Region determined the demonstrations had an impact on the state's ability to meet a NAAQS.

2. Currently your agency does NOT allow the public to see how many stratospheric intrusion events have been submitted to the EPA, including the response. Is this correct? Will you commit today to establishing a publicly accessibly website that shows when demonstrations were submitted and EPA's response?

Response to Question 2:

Because states submit exceptional events demonstration packages directly to their reviewing EPA regional office, there is no central or national tracking system for the submission and review of exceptional events requests. Some air agencies and EPA regions have developed their own processes, systems, and criteria to track exceptional event-related information. EPA is available to work with Members and will continue to work with the states to act on submissions that both states and EPA agree are priorities.

QUESTIONS FOR THE RECORD
The Honorable Suzanne Bonamici (D-OR)
U.S. House Committee on Science, Space, and Technology
Examining EPA's Regulatory Overreach
Monday, July 27, 2015

Questions for Administrator McCarthy

1. **When Congress passed legislation authorizing the creation of a Renewable Fuel Standard (RFS), one of the objectives was to diversify the nation's transportation fuel supply with domestic, renewable fuel. The RFS has effectively driven the development of renewable fuel, particularly conventional ethanol and biomass-based diesel, and created thousands of jobs in the renewable energy economy. Providing obligated parties and renewable fuel producers with certainty will help to ensure this progress continues and to further promote innovation for advanced renewable fuels, including cellulosic biofuels. Some stakeholders argue that EPA, as the implementing agency for the RFS, can do more to provide such certainty. When Congress passed the RFS, it provided EPA with waiver authority. More specifically, Congress authorized EPA to issue a general waiver of the RFS requirements, in whole or in part, if there is inadequate domestic renewable fuel supply to meet the mandate, and if implementation of the requirement would severely harm the economy or environment of a state, a region, or the United States. I am concerned that EPA's proposed standards for 2014, 2015, and 2016 for the RFS would limit renewable fuel volume requirements based, in part, on perceived constraints in the available infrastructure for distributing, blending, and dispensing renewable fuels, which some argue is outside the scope for implementing a general waiver. Can you explain why the EPA, in its proposed rule, is considering renewable fuel distribution infrastructure as a qualifying factor to issue a general waiver?**

Response to Question 1:

Congress specified increasing annual volume objectives under the RFS program for total renewable fuel, advanced biofuel, and cellulosic biofuel for every year through 2022, and for biomass-based diesel (BBD) through 2012, and authorized EPA to set volume objectives for subsequent years after consideration of several specified factors. As your question acknowledges, however, Congress recognized that circumstances could arise that might require a reduction in the volume objectives specified in the statute, as evidenced by the waiver provisions in section 211(o)(7) of the Clean Air Act.

As discussed in detail in the proposed rulemaking, we believe that limitations in production or importation of qualifying renewable fuels, *and* factors that limit supplying those fuels to the vehicles that can consume them, both constitute circumstances that could warrant a waiver under section 211(o)(7). With respect to infrastructure, the limited number and geographic distribution

of retail stations that offer higher ethanol blends such as E15 and E85, the number of flex fuel vehicles that have access to E85, as well as other market factors, combine to place significant restrictions on the volume of ethanol that can be supplied to vehicles at the present time. Stated differently, EPA believes it is appropriate to consider not only the production of the fuel, but also how much of that can be supplied to the consumer given real-world constraints. Based on our assessment of the maximum amount of renewable fuel that can be supplied in 2014, 2015 and 2016 in light of these constraints, we believe that circumstances exist that warrant a reduction in the statutory applicable volumes of advanced biofuel and total renewable fuel for 2014, 2015 and 2016.

We note that we are proposing to use the waiver authorities in a limited way that reflects our understanding of how to reconcile real marketplace constraints with Congress' intent to promote growth in renewable fuel use over time.

QUESTIONS FOR THE RECORD
The Honorable Eddie Bernice Johnson (D-TX_
U.S. House Committee on Science, Space, and Technology
(*Examining EPA's Regulatory Overreach*, July 27, 2015)

1.(a) Can you please describe the importance of ensuring the independence of the Science Advisory Board and other federal advisory committees from the agency and others; and

(b) What role, if any, does FACA play in maintaining this independence?

Response:

(a) Federal advisory committees (FACs) provide an invaluable service to the EPA as a source of scientific technical advice from diverse perspectives on matters critical to the agency's mission. Scientific and technical FACs such as the EPA Science Advisory Board (SAB) are essential venues for incorporating the ongoing dialogue in the broader scientific community and often are the route of choice for implementing rigorous, independent peer review of the scientific analyses designed to support EPA programs and decisions.

(b) The Federal Advisory Committee Act (FACA) directs agency heads establishing federal advisory committees (FACs) to assure that the advice of the FAC will be the result of its independent judgment, and not be inappropriately influenced by the agency that appoints the members or any special interest. For the SAB, this independence is critical to the credibility of the SAB's scientific findings and recommendations. Consistent with FACA's requirement that agencies establish administrative guidelines and management controls for its FACs, the EPA has developed a FACA Handbook, which outlines how the Agency appoints the members of its advisory committees, including the SAB, and, in the formal charter filed with Congress, the EPA describes the broad scope of the SAB's activities. Once a request for advice (or "charge") has been provided to the SAB, the Agency has procedural policies (consistent with the letter and spirit of FACA) designed to guard against inappropriate influence by the EPA or outside interests on the deliberations and conclusions of the SAB and its panels and committees in response to that charge.